MAY 20 1996 K960920

Picker 510(k) Notice

Clinix mp

Summary of Safety and Effectiveness

This is a summary of the information submitted by Picker International, Inc. to the Office of Device Evaluation (DRAERD) of the FDA as required by the Federal Food, Drug, and Cosmetic Act as amended on November 18, 1990 in section 513(f)(3) for the Universix 190.

The *Clinix mp* is a remote controlled R/F X-ray system intended for radiographic/ fluoroscopic examinations of the entire human anatomy. This device may include signal analysis and display equipment, patient equipment supports, components and accessories.

Functional specifications and operator's instructions (preliminary) are included in the attachments. Final documentation will be provided with production units.

The *Clinix mp* is substantially equivalent to legally marketed devices. The *Clinix mp* is under control of health care professionals who are trained and responsible for fluoroscopic examinations. The *Clinix mp* will be certified to comply with Federal Diagnostic X-ray Performance Standards. Labeling (Product Bulletin and Operator's Manual) will be provided to the user of the equipment.

MECALL adheres to FDA GMPs, 21 CFR 1020.30-31, voluntary standards for safety/effectiveness (UL 187) all of which mandate that components are tested to minimize hazards (electrical, mechanical, and radiation).

Effectiveness is established by MECALL's evaluation throughout all phases of the *Clinix mp* development. The product will perform in accordance with the development specifications. The *Clinix mp* represents the current state-of- the-art technology, therefore, is equivalent to legally marketed remote C-arm systems.

MECALL has reviewed all known information and performed an investigation as to the causes of safety/effectiveness concerning the *Clinix mp*. In addition, all information contained in this 510(k) Notice is accurate and complete.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Robert L. Turocy
Regulatory Compliance Manager
Picker International, Inc.
World Headquarters
595 Miner Road
CLEVELAND OH 44134

FEB 19 2013

Re: K960920
Trade/Device Name: Clinix mp
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB and JAA
Dated: March 5, 1996
Received: March 6, 1996

Dear Mr. Turocy:

This letter corrects our substantially equivalent letter of May 20, 1996.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K960920

Device Name: *Clinix mp*

Indications for Use: Routine Radiolgraphic/Fluoroscopic examinations of the entire human anatomy, gastrointestinal tract, full vascular/interventional capabilities, and organ examinations.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K960920

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)